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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,562	06/24/2003	Michael N. Alekshun	PAZ-190	8041
959	7590	11/29/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,562	ALEKSHUN ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is assigned to Dr. Kailash C. Srivastava, in Art Unit 1655. To aid in correlating any papers for this application (i.e., USSN 10/313,643), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

Claims Status

2. Claims 1-51 are pending.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. §121:

- Group I – Claims 1-6 drawn to a method to prevent infections in a subject, classified under Class 514, Subclass 41 for example.
- Group II – Claims 7-10 drawn to a method to reduce virulence of a microorganism, classified under Class 514, Subclass 192 for example.
- Group III – Claims 11-14 drawn to a method to treat a microbial infection, classified under Class 424, Subclass 93.6 for example.
- Group IV- Claims 15 and 17-19 drawn to a method to treat urinary infection, classified under Class 424, Subclass 95.1 for example.
- Group V- Claim 16 drawn to a method to treat prostatitis, classified under Class 424, Subclass 114 for example.
- Group VI- Claims 20-23 drawn to a method to inhibit virulence in a microbe via administering a compound that inhibits expression of transcription factor, classified under Class 514, Subclass 200 for example.
- Group VII- Claims 24-29 drawn to a method to evaluate the effectiveness of a compound to modulate expression or activity of a transcription factor, classified under Class 424, Subclass 9.1 for example.
- Group VIII- Claims 30-34 drawn to a method to identify a compound to treat a microbial infection, classified under Class 424, Subclass 94.61 for example.

- Group IX- Claims 35-39 drawn to a method to identify a compound to reduce microbial virulence, classified under Class 424, Subclass 404 for example.
- Group X- Claims 40-44 drawn to a method to identify transcription factors promoting microbial virulence, classified under Class 424, Subclass 418 for example.
- Group XI- Claims 45-49 drawn to a method to reduce the ability of a microbe to reduce to an abiotic surface, classified under Class 424, Subclass 94.1 for example.
- Group XII- Claim 50 drawn to a pharmaceutical composition, classified under Class 435, Subclass 69.2 for example.
- Group XIII- Claim 51 drawn to a pharmaceutical composition comprising an antibiotic and a modulation compound for modulating microbial transcription factor, classified under Class 514, Subclass 12 for example.

Inventions are Independent and Distinct

4. The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-XI are unrelated to each other because they are directed to different inventions that are not connected in design, operation/ contents and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group I are directed to a method that will not encompass the same steps or produce the same effect as for example the composition encompassed in Group V invention, and would therefore, may not be practiced together.

Inventions in Groups XII and XIII are related to invention in Groups I-XI as product and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. In the instant case the method of Group I encompassing Claims 1-6 is applicable to treat any microbial infection in any subject, not just the urinary tract infection. Likewise, said urinary tract infection is treated with a number of over the counter/ other prescription compositions.

Inventions in Groups XII-XIII are related to each other as sub-combinations disclosed as usable together in a single combination. The sub-combinations are distinct from each other if they are shown to be separately usable. In the instant case, an invention in each of Groups XII-XIII has separate utility. For

example invention in Group XII is a mixture of a compound that modulates the transcription factor in a microbe and a pharmaceutical carrier and as such application of said mixture to an individual in need thereof will be applicable to treat a microbial infection. The invention ascribed to Group XIII is a composition comprising ingredients of the composition in Group XII invention and additionally comprises and antibiotic, said mixture having the same or similar effect in a subject in need thereof as the mixture of the composition encompassed in claim for invention XII.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and their recognized diverse subject matter, they would illicit an undue burden on the examiner to search and examine all the inventions in groups I-IV in one single application. Furthermore, the criteria for patentability may not be same for each of the recited groups and what may be applicable for one group may not at all be applicable to other group. Thus, restriction for examination purposes as indicated is proper.

5. Applicants are advised that a reply to this requirement must include an identification of an invention elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of additional claims which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. Currently, Claims 1, 5-7, 11, 15-16, 20, 24, 30, 35, 40, 45, 50 and 51 are generic claims. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b). Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:00 A.M. to 4:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1655
(571) 272-0923

November 21, 2005



RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200